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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/639,289	08/15/2000	Mahendra G. Dedhiya	10/042	1566

7590

11/19/2001

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EXAMINER

WELLS, LAUREN Q

ART UNIT

PAPER NUMBER

1619

DATE MAILED: 11/19/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/639,289

Applicant(s)

DEDHIYA ET AL.

Examiner

Lauren Q Wells

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Claims 1-22 are pending. Claims 1-4 were amended per the Amendment received October 15, 2001, Paper No. 9. Claims 11-22 were added per the Amendment received October 15, 2001, Paper No. 9.

Response to Applicant's Arguments/Amendment

The Applicant's arguments filed October 15, 2001 (Paper No. 9) to the rejection of claims 1-10 made by the Examiner under 35 USC 103 have been fully considered and deemed not persuasive. The Applicant's amendments filed October 15, 2001 (Paper No. 9) to claims 1-4 have overcome the 35 USC 112 rejections. Therefore, the said rejection is hereby withdrawn.

103 Rejection Maintained

The rejection of claims 1-10 and newly added claims 11-22 under 35 U.S.C. 103(a) as being unpatentable over Touitou (5,716,638) in view of Peart et al. (WO 00/24362) and Vachon (XP-000965573) in further view of Allison's Apothecary is MAINTAINED for the reasons set forth in the Office Action mailed June 15, 2001, Paper No. 5, and those found below.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant argues, "Touitou provides no suggestion or teaching of how these topical liposomal composition would be administered by inhalation or aerosolized at a mean mass median aerodynamic diameter" and that "there is no expectation of success when combining the teaching of Touitou with that of Peart et al and Vachon in further view of Alison's Apothecary".

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This argument is not persuasive. First, Touitou teaches pharmaceutical compositions for delivery to tissues (see Col. 1, lines 6-32). The Examiner respectfully points out that the lung can be broadly described as a tissue.

Second, the teachings of Touitou were not relied upon solely for the rejection of the claims of the instant invention. Touitou was combined with Peart and Vachon. Touitou teaches that tetrahydrocannabinol can exist in composition with ethanol, propylene glycol and water. Peart and Vachon both teach that it is known in the art to aerosolize compositions comprising tetrahydrocannabinol as active agents. Peart further teaches compositions comprising tetrahydrocannabinol, ethanol and propylene glycol. Vachon further teaches compositions comprising tetrahydrocannabinol, propylene glycol and water. The Examiner respectfully points out that it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 USPQ 1069 (CCPA 1980). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Peart and Vachon to teach the composition of Touitou in the form of an aerosol because a) Touitou teaches compositions comprising tetrahydrocannabinol, water, propylene glycol, and ethanol and Peart teaches that it is known to combine tetrahydrocannabinol with ethanol and propylene glycol and Vachon teaches that it is known to combine tetrahydrocannabinol with propylene glycol and water; b) all references teach their compositions for delivery of tetrahydrocannabinol in vivo; c) Peart teaches that the optimal size of a respirable droplet is less than 10um in size and Touitou teaches his composition as having particles sizes less than 10um; d) Vachon teaches as generating an aerosol with particles

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having a mean diameter ranging between 0.5-2.5um and Touitou teaches his composition as having particle sizes within this range.

Third, this argument is not commensurate in scope with independent claim 1. The phrase "sufficient" is not a positive recitation, hence the composition described above this phrase is not bound to be in the form of an aerosol. Furthermore, the Examiner respectfully points out that a recitation of the intended utility ("by inhalation") in the preamble does not impart patentability of a known composition. In re Spada, 911 F.2d 705, 15 USPQ 2d 1655 (Fed. Cir. 1990).

In regards to Applicant's arguments of unexpected results, this argument is not persuasive. It is the Examiner's position that it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Touitou, Peart and Vachon to arrive at the composition of the instant invention. The Examiner furthermore respectfully points out that it is well settled that a patent cannot be granted for an applicant's discovery of a result, even though it may be unexpectedly good, which would flow logically from the teaching of the prior art.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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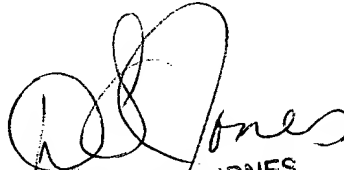
CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on T-F (6-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana L Dudash can be reached on (703) 308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw
November 2, 2001



DAMERON L. JONES
PRIMARY EXAMINER